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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,677	10/06/2004	Mark Parrington	API-01-20-US	4967
7590 Patrick J Halloran Aventis Pasteur Inc Intellectual Property Kenerr Bldg One Discovery Drive Swiftwater, PA 18370				
EXAMINER AEDER, SEANE				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
06/12/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/510,677

**Applicant(s)**

PARRINGTON ET AL.

**Examiner**

SEAN E. AEDER

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30, 36 and 38-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 44 is/are allowed.
- 6) ☒ Claim(s) 1-30, 38-43, and 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Detailed Action***

The Amendments and Remarks filed 5/18/09 in response to the Office Action of 11/17/08 are acknowledged and have been entered.

Claims 1-30, 36, and 38-50 are pending and are currently under examination.

***Response to Arguments***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-30 and 38-43 remain rejected under 35 U.S.C. 101 for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Claims 1-30 and 38-43, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The term "expression vector" does not indicate the hand of man is required. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". *See* MPEP 2105.

In the Reply of 5/18/09, Applicant argues that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences. Applicant

further argues that compositions comprising expression vectors and pharmaceutical compositions are not naturally occurring.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences, not every DNA sequence which has occurred naturally or will occur naturally is known. Therefore, polynucleotides comprising SEQ ID NO:28 encompass naturally occurring polynucleotides which either have or will occur. In regards to the argument that comprising expression vectors are not naturally occurring, viruses are naturally occurring expression vectors. In regards to the argument that pharmaceutical compositions are not naturally occurring, claims reciting that a product is a pharmaceutical composition indicates an intended use and is not considered a limitation to a claim.

It is noted that amending claims 1, 26, and 38 by placing the word "isolated" before "nucleic" would obviate this rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al (US Patent 5,833,975; 11/10/98) for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Paoletti et al teaches ALVAC poxvirus vectors comprising CEA antigen-encoding SEQ ID NO:145, which shares greater than 80% homology with instant SEQ ID NO:28, and the full complement thereof (see abstract and sequence comparison below, in particular). Paoletti et al further teaches said vectors further comprising a nucleic acid sequences including the costimulatory molecule B7.1 (line 58 of column 14, in particular). Paoletti et al further teaches compositions comprising said vectors and pharmaceutically acceptable carriers (see line 22 of column 8, in particular). In regards to instant claims 45-50, it is noted that the nucleic acids of SEQ ID NO:145 includes all nucleic acids of 421-1490 of SEQ ID NO:28 (A, T, G, and C).

In the Reply of 5/18/09, Applicant argues that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28, the nucleic acids of claims 45-50 are not required to comprise the sequence set-forth as SEQ ID NO:28. Rather, the nucleic acids of claims 45-50 require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28. The nucleic

acids of claims 45-50 do not require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28 in any particular order.

It is noted the following amendments to claim 45 would obviate this rejection: "An isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least the sequence set-forth by nucleotides 421-1490 of SEQ ID NO.:28".

Comparison of instant SEQ ID NO:28 and SEQ ID NO:145 of Paoletti et al:

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Query Match          80.6%; Score 1697.8; DB 2; Length 2349;
  Best Local Similarity 88.1%; Pred. No. 0;
  Matches 1859; Conservative 0; Mismatches 247; Indels 3; Gaps
1;

Qy          1 ATGGAGTCTCCCTCGGCCCTCCCCACAGATGGTGCATCCCTGGCAGAGGCTCCTGCTC 60
  |||
Db          184 ATGGAGTCTCCCTCGGCCCTCCCCACAGATGGTGCATCCCTGGCAGAGGCTCCTGCTC
243

Qy          61 ACAGCCTCACTTCTAACCTTCTGGAACCGCCACCAGCTGCCAAGCTCACTATTGAATCC
120
  |||
Db          244 ACAGCCTCACTTCTAACCTTCTGGAACCGCCACCAGCTGCCAAGCTCACTATTGAATCC
303

Qy          121 ACGCGGTTCAATGTGCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCACAACTGCCCCAG
180
  |||
Db          304 ACGCGGTTCAATGTGCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCACAACTGCCCCAG
363

Qy          181 CATCTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
240
  |||
Db          364 CATCTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
423

Qy          241 GGATATGTAATAGGAACCTAACAAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
300
  |||
Db          424 GGATATGTAATAGGAACCTAACAAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
483
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Art Unit: 1642

[illegible]

Qy 900	841	ACCCAGGAAC TGTTCATTCCCAATATTACCGTGAACAATAGTGGATCTACACGTGCCAA
Db 1083	1024	ACCCAAGAGCTCTTTATCCCCAACATCACTGTGAATAATAGTGGATCTATACGTGCCAA
Qy 957	901	GCTCACAATAGCGACACCGGACTCAACCGCACAAACCGTGACGACGATTACCGTGTAT---
Db 1143	1084	GCCCATAACTCAGACACTGGCCTCAATAGGACCACAGTCACGACGATCAGTCTATGCA
Qy 1017	958	GAGCCACCAAAAACCATTCATAACTAGTAACAATTTCTAACCCAGTTGAGGATGAGGACGCA
Db 1203	1144	GAGCCACCCAAAACCTTTCATACCAGCAACAACCTCAACCCCGTGAGGATGAGGATGCT
Qy 1077	1018	GTTGCATTAACTTGTGAGCCAGAGATTCAAAATACCACCTATTATTTATGGTGGGTCAATAAC
Db 1263	1204	GTAGCCTTAACCTGTGAACCTGAGATTGAGAACACAACCTACCTGTGGTGGGTAAATAAT
Qy 1137	1078	CAAAGTTTGCCGGTTAGCCACGCTTGCAAGTTGTCTAATGATAACCGCACATTGACACTC
Db 1323	1264	CAGAGCCTCCCGGTGAGTCCCAGGCTGCAGCTGTCCAATGACAACGAGACCCCTCACTCTA
Qy 1197	1138	CTGTCCGTTACTCGCAATGATGTAGGACCTTATGAGTGTGGCATTGAGAATGAATTATCC
Db 1383	1324	CTCAGTGTCAACAAGGAATGATGTAGGACCTTATGAGTGTGGAATCCAGAACGAATTAAGT
Qy 1257	1198	GTTGATCACTCCGACCCTGTTATCCTTAAATGTTTGTATGGCCCAGACGACCCAACATATA
Db 1443	1384	GTTGACCACAGCGACCCAGTCATCTGAAATGTCTCTATGGCCCAGACGACCCACCATT
Qy 1317	1258	TCTCCATCATACACTACTACCGTCCCGGCGTGAACCTTGAGCCTTTCTTGCCATGCAGCA
Db 1503	1444	TCCCCCTCATACACTATTACCGTCCAGGGGTGAACCTCAGCCTCTCTGCCATGCAGCC
Qy 1377	1318	TCCAACCCCCCTGCACAGTACTCCTGGCTGATTGATGGAAACATTACGACGATACTCAA
Db 1563	1504	TCTAACCCACCTGCACAGTATTCTTGGCTGATTGATGGGAACATCCAGCAACACACACA





Art Unit: 1642

Qy 1918 TTTATCGCCAAAATCAGCCAAATAATAACGGGACCTATGCCTGTTTGTCTCTAACTTG  
 1977  
 |||  
 Db 2104 TTTATCGCCAAAATCAGCCAAATAATAACGGGACCTATGCCTGTTTGTCTCTAACTTG  
 2163  
 |||  
 Qy 1978 GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAACCTCT  
 2037  
 |||  
 Db 2164 GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAACCTCT  
 2223  
 |||  
 Qy 2038 CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT  
 2097  
 |||  
 Db 2224 CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT  
 2283  
 |||  
 Qy 2098 CTGATATAG 2106  
 |||  
 Db 2284 CTGATATAG 2292

***Allowable Subject Matter***

Claims 36 and 44 are allowed.

***Summary***

Claims 1-30, 38-43, and 45-50 are rejected.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/

Application/Control Number: 10/510,677

Page 11

Art Unit: 1642

Primary Examiner, Art Unit 1642